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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,981	04/14/2004	Patrick Benoit	A-72230-2	8002
7278	7590	01/30/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/824,981

Applicant(s)

BENOIT ET AL.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/240265.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/3/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 1-15 are pending.
2. Applicants' Response to Restriction filed on 11/16/05 is acknowledged.  
Applicants' election of species reads on antiproliferative activity of IFN-R monoclonal antibody without traverse is acknowledged.

Accordingly, claims 11-12 are withdrawn from the further consideration by examiner 37 CFR.1.142 (b) as being drawn to a non-elected species.

Claims 1-10 and 13-15 drawn to a method for neutralizing biological property of IFN are under consideration in the instant application.

3. Applicants' claim for foreign priority under 35. U.S.C. 119(a)-(d) is acknowledged.  
The certified copy has been filed in parent application no. 09/240,675 filed on 2/2/99.
4. Applicants' IDS filed on 9/3/04 is acknowledged.
5. Applicant is required to update US priority in the first line of the specification and update status of all pending applications.
6. Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).
7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 5-8 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.  
The phrase "inferior to" in claims 5-8 is not quantitative but rather qualitative in describing antibody concentration ranges.

Art Unit: 1644

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The antibody recited in ECACC Accession number 92022605 is essential to the claimed invention. The reproduction of antibodies from the disclosed hybridoma is an extremely unpredictable event. The monoclonal antibody recited in ECACC Accession number 92022605, disclosed on page 8 ([0043]) of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the hybridomas, and it is not apparent if the hybridomas are readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridomas have been deposited under the Budapest Treaty **and that the hybridomas/antibodies will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808.** Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent whichever is longer.** See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

Art Unit: 1644

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the hybridoma described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-10 and 13-14 rejected under 35 U.S.C. 102(e) as being anticipated by the U.S. Pat. No. 5,516,515.

The '515 patent teaches a method for neutralizing antiproliferative activity by contacting of anti-IFN $\alpha$ 2 receptor monoclonal antibodies to cells expressing IFN receptors (monoclonal, col. 9, lines 1-33, i.e. antibodies produced by NS-1 hybridoma; antiproliferative activity, col. 3, lines 15-24, i.e. quantifying IFN receptors on a select cell population, col. 2, lines 51-55, col. 3, lines 14-29, col. 1, lines 19-23).

The '515 patent further teaches IFN receptors are expressed on blood lymphocytes as well as tumor cells including Daudi cells (col. 3, lines 18-19, col. 4, lines 7-19), the receptors not binding to IFN- $\gamma$  (Fig. 3, col. 5, under binding assay) and recombinant, soluble IFN receptor proteins (col. 6 under affinity purification, col. 4, lines 22-40).

Art Unit: 1644

As is evidenced in p. 15 of the specification of the instant application, the claimed type I IFN receptor is IFN $\alpha$ 2, thus the epitope of amino acid residues of 27-427 of IFN $\alpha$ 2 is encompassed in the referenced teaching. Further evidenced in [0077], p. 15 of the instant specification, the antibody concentration ranges of 0.1 to 1.5 ug/ml exhibits Kd of  $\sim 10$ nM, the claimed limitation of "antibody concentration in the range of about 0.5-2ug/ml" is met in col. 7, lines 42-46 (i.e.  $8 \times 10^{-11}$  and  $1 \times 10^{-9}$  M).


Claims 10 and 14 are included in this rejection as the '515 teaches IFN receptor expressing blood lymphocytes which read on Ly28 cells and the same antigen (IFN $\alpha$ 2 receptor) used to prepare monoclonal antibody in the same myeloma cell lines (NS-1, col. 9, lines 20-35 and [0069] of the instant application), having IgG1 (most ubiquitous among IgG isotypes) isotype is inherent property of anti IFN $\alpha$ 2 receptor monoclonal antibody. Thus, the reference teachings anticipate the claimed invention.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim  
Patent Examiner  
Technology Center 1600  
January 20, 2006

  
Patrick J. Nolan, Ph.D.  
Primary Examiner  
Technology Center 1600